K081913

XII.1

510(k) SUMMARY (Metacem)

SEP - 5 2008

Submitter: Tae-Hoon Kim, Manager QM, Meta Biomed Co., Ltd, Cheongwongun Chungbuk, Korea. Tel: 82-43-218-1983.

I. Classification Name and Number: Dental Cement, 872.3275, Code EMA, Class II.

II. Common/Usual Name: Dental cement, cement,

III. Proprietary Name: Metacem

IV. Registration No.: 9681254

V. Compliance with Performance Standards: No Section 514 performance standards are applicable. However, Metacem meets ISO 4049:2000(E)7.5, 7.7, 7.8, 7.11, 7.12, 7.13, and 7.14 for physical properties and ISO 10993-5, -6, -10, and -11 for biocompatibility.

VI. Description of the Device: Metacem is a high strength, permanent visible light cured (VLC), dual cured or self-cured resin cement for use with dentin/enamel adhesive prime and bond systems, to adhesively bond and lute indirect restorations to tooth structure. Metacem consists of a methacrylate base paste and catalyst paste which in use are instantly mixed from a dual syringe to form a dual-cured cement. This mixed version of the cement will self-cure or can be light cured, or both. The dual cure is effective for high shade, thick or opaque cementation.

Metacem is meant to be used with the Meta P&Bond system (or other equivalent system which should be tested before use) and with Metacem Silane Ceramic Primer for priming ceramic surfaces before use of Meta P&Bond, then Metacem.

VII. Labels and Labeling: Draft labels of Metacem packages and instructions for use are provided, together with warnings and contra-indications.

VIII. Substantial Equivalence: This device is equivalent to devices manufactured and sold before 1976, having a U. S. classification number (code) EMA, and described under 21 CFR 872.3275. Metacem is also equivalent to several devices currently on the market that have been cleared by the premarket notification—510(k) process. Some of these are outlined below:

1. K073173, Self-Adhesive Resin Cement, Dentsply, Intl.,
2. K060703, Biscem Translucent, Biscem Opaque, Bisco, Inc.,
3. K060698, Cement-It All Purpose, Pentron Clinical Technologies,
4. K053040, Paracem Universal DC, Coltene/Whaledent AG, and
5. K040906, Calibra Cement, Dentsply, Intl.

Metacem is substantially equivalent to Calibra (K040906) cement and others listed above, such as Biscem Translucent...(K060701) by Bisco, Inc..Metacem is quite similar to Calibra; both may be light cured (VLC), dual cured or self-cured and are high strength cements, that, when used with compatible dentin/enamel adhesive systems, adhesively bond and lute indirect restorations to tooth structures. Like several other predicates, they both consist of VLC base paste and catalyst paste. Therefore the mixed version of the cement will self-cure or can be light-cured, or both. Like Calibra cement, Metacem has a high viscosity to avoid run off of a restoration during placement and proper flow properties to provide easy handling. Also, both products have the same indications for use.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed.

(End of Summary)

XII.2 **510(k) SUMMARY (Meta P&Bond)**

Submitter: Tae-Hoon Kim, Manager QM, Meta Biomed Co., Ltd, Cheongwongun Chungbuk, Korea. Tel: 82-43-218-1983.

I. Classification Name and Number: Resin Tooth Bonding Agent, 872.3200, Code KLE, Class II.

II. Common/Usual Name: Primer, prime and bond.

III. Proprietary Name: Meta P&Bond

IV. Registration No.: 9681254

V. Compliance with Performance Standards: No Section 514 performance standards are applicable. However, Meta P&Bond meets applicable parts of ISO 4049:2000 and ISO 11405, for properties, and ISO 10993 for biocompatibility.

VI. Description of the Device: Meta P&Bond is a wet bond adhesive system that is activated by visible light curing. This bonding agent is one-step for priming and bonding. It is formulated to adhesively bond to hard surfaces of the oral cavity, namely enamel and dentin, for use with dental cements like Metacem. It is useful as a primer for use with other methacrylate cements such as Calibra and equivalent products. It is intended to be painted on the interior of a prepared cavity or surface of a tooth to improve retention of a restoration such as a filling or crown. It also is useful as a prime and bonder for porcelain veneer luting, bonding composite to composite, and composite to metal/amalgam.

VII. Labels and Labeling: Draft labels of Meta P&Bond and instructions for use are provided, together with warnings and contra-indications.

VIII. Substantial Equivalence: This device is equivalent to devices manufactured and sold before 1976, having a U. S. classification number (code) KLE, and described under 21 CFR 872.3200. Meta P&Bond is also equivalent to several devices currently on the market that have been cleared by the premarket notification—510(k) process. Some of these are outlined below:

1. K070215, Tokuyama Bond Force, Tokuyama Dental Corp.,
2. K063557, Peak Bond, Ultradent Products, Inc.,
3. K011159, One-Step Plus, Bisco, Inc. and
4. K960823, Prime & Bond 2.0 Multipurpose, Dentsply, Intl.

Meta P&Bond is substantially equivalent (and most similar) to One-Step Plus (K011159) by Bisco, Inc. It is also equivalent to several other primer-and-bond agents as listed above. It is substantially equivalent to Peak Bond (K063557) by

Ultradent. Like Peak Bond, Meta P&Bond, has an ethanol carrier, is a wet bond adhesive, light-curing resin. It is perhaps most similar to One-Step Plus (K011159) by Bisco, Inc. The major attribute of these products is their effective adhesive bonding to dentin and enamel, and radio-opacity and ease of use. Both Meta P&Bond and One-Step Plus (K011159) are filled, low-viscosity resins. Meta P&Bond is substantially equivalent to the several competitive devices cited in respect to biocompatibility and bond strength. Although these predicates, and Meta P&Bond may differ slightly in performance characteristics, the differences to not raise new questions of safety and effectiveness.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed.

(End of Summary)

XII.3 **510(k) SUMMARY (Metacem Silane Ceramic Primer)**

Submitter: Tae-Hoon Kim, Manager QM, Meta Biomed Co., Ltd, Cheongwongun Chungbuk, Korea. Tel: 82-43-218-1983.

I. Classification Name and Number: Resin Tooth Bonding Agent, 872.3200, Code KLE or EBF, Class II (accessory).

II. Common/Usual Name: Ceramic primer, priming agent

III. Proprietary Name: Metacem Silane Ceramic Primer.

IV. Registration No.: 9681254

V. Compliance with Performance Standards: No Section 514 performance standards are applicable.

VI. Description of the Device: Metacem Silane Ceramic Primer is an organic substituted silicone material especially designed to provide an improved surface on porcelain, ceramics, composite resins that are to be treated with Meta P&Bond and then cemented to tooth structure. It also is designed to improve the adhesivity of surfaces involved in the repairs of fractured porcelain, ceramics or composite resin crowns or bridges. It is a low viscosity liquid with high volatility.

VII. Labels and Labeling: Draft labels of Metacem Silane Ceramic Primer and instructions for use are provided, together with warnings and contra-indications.

VIII. Substantial Equivalence: This device (accessory) is equivalent to similar devices manufactured and sold before 1976, having a U. S. classification number (code) EMA, and described under 21 CFR 872.3275. It is also equivalent to several devices currently on the market that have been cleared by the premarket notification—510(k) process. Some of these are outlined below

1. K061906, Clearfil CeramicPrimer, Kuraray Medical Inc.,
2. K061322, Porcelain Primer, J. Morita USA, Inc.,
3. K024356, Clearfil Silane Kit, Kuraray Medical Inc. and
4. K954708, Silane Primer, Sybron Dental Specialties, Inc.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2008

Mr. Tae-Hoon Kim
Quality Manager
Meta Biomed Company, Limited
414-12 Mo Choong Dong
Cheung Ju City, Chung Buk,
Republic of Korea 441-12

Re: K081913
Trade/Device Name: Metacem, Meta P&Bond, Metacem Silane Ceramic Primer
Regulation Number: 872.3200
Regulation Name: Resin Tooth bonding Agent
Regulatory Class: II
Product Code: KLE, EMA
Dated: June 20, 2008
Received: July 3, 2008

Dear Mr. Hoon Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for/CC

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

XI.1. Indications for Use: [Separate Page]

510(k) Number: NA

Device Name: Metacem

Indications for use:

Adhesive cementation of:

- Crowns & Bridges (ceramic, porcelain, composite and metals),
- Inlays/onlays cementation ,
- Bonding of veneers or crown; PFM, also alumina & zirconia,
- Endodontic post cementation,
- Core build up.

Prescription Use___X___ (Per 21 CFR 801 Subpart D) or Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081913

XI.2 Indications for Use: [Separate Page]

510(k) Number: NA

Device Name: Meta P&Bond

Indications for use:

- A dental adhesive formulated to adhesively bond to hard tissues of the oral cavity, enamel and dentin,
- Dentin-enamel primer/bonding agent for direct composite restorations
- Indirect composite restorative luting system
- Porcelain veneer luting system
- Bonding composite to composite
- Bonding composite to metal/amalgam
- Adhesive amalgam restoration.

Prescription Use__X__ (Per 21 CFR 801 Subpart D) or Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K084913

XI.3 Indications for Use: [Separate Page]

510(k) Number: NA

Device Name: Metacem Silane Ceramic Primer

Indications for use:

Primer for surfaces of:

- Crowns and bridges, ceramic, composite, porcelain, metal,
- Pre-cured composite inlays and onlays,
- Ceramic inlays and onlays,
- Porcelain veneers,
- Porcelain and metal prosthesis

Prescription Use___X___ (Per 21 CFR 801 Subpart D) or Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 11

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K083113